UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

May 6, 2002

MEMORANDUM

SUBJECT: **Diazinon** [PC Code 057801], Acute Mammalian Toxicity Batching Appendix for Chem Name RED Document.

FROM: Hari M. Mukhoty, DVM, PhD
Product Reregistration Branch
Special Review and Reregistration Division (7508W)

TO: John Hebert, CRM
Reregistration Branch II
Special Review and Reregistration Division (7508W)

Attached is the batching appendix for Diazinon. Please let me know if you have any questions regarding this document.

EPA'S BATCHING OF **DIAZINON** PRODUCTS FOR MEETING ACUTE TOXICITY DATA

REQUIREMENTS FOR REREGISTRATION

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing **DIAZINON** as the active ingredient, the Agency has batched products which can be considered similar for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

Using available information, batching has been accomplished by the process described in the preceding paragraph. Notwith-standing the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should the need arise.

Registrants of products within a batch may choose to cooperatively generate, submit or cite a single battery of six acute toxicological studies to represent all the products within that batch. It is the registrants' option to participate in the process with all other registrants, only some of the other registrants, or only their own products within a batch, or to generate all the required acute toxicological studies for each of their own products. If a registrant chooses to generate the data for a batch, he/she must use one of the products within the batch as the test material. If a registrant chooses to rely upon previously submitted acute toxicity data, he/she may do so provided that the data base is complete and valid by today's standards (see acceptance criteria attached), the formulation tested is considered by EPA to be similar for acute toxicity, and the formulation has not been significantly altered since submission and acceptance of the acute toxicity data. Regardless of whether new data is generated or existing data is referenced, registrants must clearly identify the test material by EPA Registration Number. If more than one confidential statement of formula (CSF) exists for a product, the registrant must indicate the formulation actually tested by identifying the corresponding CSF.

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies

and offering to cost share (Option 3) those studies.

One hundred and fifty five products were found which contain Diazinon as the active ingredient. These products have been placed into four batches and a "no batch" category in accordance with the active and inert ingredients and type of formulation. Furthermore, the following bridging strategies are deemed acceptable for this chemical:

- Batch 11: The representative eye studies for this batch should be conducted on EPA Reg. 572-292,9198-62, or 32802-5.
- Batch 12: The representative acute toxicity studies (except primary eye study) should be conducted on the products with the highest percentage of active ingredient. A primary eye irritation study should be conducted on each product listed in this batch.
- Batch 14: EPA Reg. Nos. 3546-27 & 19713-317 may cite data conducted on EPA Reg. No. 6218-69 or 10088-71.
- No Batch: Each product in this Batch should generate their own data.

NOTE: The technical acute toxicity values included in this document are for informational purposes only. The data supporting these values may or may not meet the current acceptance criteria.

Batch 1	EPA Reg. No.	% Active Ingredient
	11678-61	92.0
	11678-62	92.0
	100-979	87.0
	100-980	87.0
	10163-263	87.0
	11678-63	87.0
	11678-64	87.0
	19713-523	87.0
	19713-524	87.0
	34822-6	87.0
	47332-4	87.0
	62366-2	87.0

Batch 2	EPA Reg. No.	% Active Ingredient
	100-784	56.0
	100-977	56.0
	10163-241	56.0

Batch 3	EPA Reg. No.	% Active Ingredient
	100-460	50.0
	655-456	50.0
	769-954	50.0
	5905-526	50.0
	10163-163	50.0
	19713-492	50.0
	34704-435	50.0
	51036-108	50.0
	66222-10	50.0

Batch 4	EPA Reg. No.	% Active Ingredient
	100-461	48.0
	655-459	48.0
	769-689	48.0
	769-841	48.0
	829-262	47.5
	1386-599	48.0
	2935-388	48.0
	5481-224	47.5
	5905-248	48.0
	9779-210	48.0
	10163-100	48.0

Batch 4	EPA Reg. No.	% Active Ingredient
	19713-91	48.0
	34704-231	48.0
	37915-6	48.0
	51036-71	48.0

Batch 5	EPA Reg. No.	% Active Ingredient
	655-462	48.7
	7401-213	48.0
	66222-9	48.0

Batch 6	EPA Reg. No.	% Active Ingredient
	19713-145	Diazinon: 25.00 Captan: 37.50
	42056-18	Diazinon: 25.00 Captan: 37.50

Batch 7	EPA Reg. No.	% Active Ingredient
	16-157	25.0
	100-456	25.0
	239-2364	25.0
	270-282	25.0
	572-305	25.0
	1386-573	25.0
	7401-216	25.0
	8845-92	25.0
	28293-230	25.0
	33912-1	25.0
	33955-556	25.0

Batch 8	EPA Reg. No.	% Active Ingredient
	16-166	22.4
	100-770	22.4
	239-2643	22.4
	869-231	22.4
	4581-392	23.0
	7401-441	22.4
	59144-28	22.4
	61282-25	22.4

Batch 9	EPA Reg. No.	% Active Ingredient
	100-469	14.3
	655-557	14.3
	10163-104	14.3
	28293-239	14.3
	34704-230	14.0

Batch 10	EPA Reg. No.	% Active Ingredient
	2935-408	14.3
	5905-262	14.3
	19713-95	14.0
	51036-70	14.3

Batch 11	EPA Reg. No.	% Active Ingredient
	16-119	5.00
	100-528	5.00
	192-161	5.00

Batch 11	EPA Reg. No.	% Active Ingredient
	228-177	5.00
	239-2479	5.00
	239-2503	5.00
	538-187	4.54
	572-292	5.00
	655-556	5.00
	829-264	5.00
	869-139	5.00
	961-358	5.00
	1386-648	5.00
	8378-32	5.00
	8750-51	5.00
	8845-95	5.00
	8845-101	5.00
	9198-62	5.00
	10163-116	5.00
	10404-23	5.00
	19713-263	5.00
	28293-199	5.00
	32802-5	5.00
	33955-557	5.00
	34704-57	5.00
	34704-493	5.00
	34911-13	5.00
	34911-23	5.00
	40849-30	5.00
	42057-107	5.00
	51036-93	5.00

Batch 11	EPA Reg. No.	% Active Ingredient
	51036-97	5.00
	53883-51	5.00
	53883-54	5.00
	59114-2	5.00

Batch 12	EPA Reg. No.	% Active Ingredient
	16-118	2.00
	100-468	2.00
	228-162	2.10
	239-2375	2.00
	538-92	2.88
	538-204	2.88
	538-254	3.67
	538-258	3.20
	1386-651	2.00
	7401-222	2.00
	8378-12	3.33
	8660-11	3.34
	8780-54	2.10
	8780-55	3.30
	9198-45	3.33
	9688-89	2.00
	10404-14	3.33
	19713-264	2.00
	51036-69	2.00
	53883-46	2.00

Batch 13	EPA Reg. No.	% Active Ingredient
	100-926	2.0
	239-2671	2.0

Batch 14	EPA Reg. No.	% Active Ingredient
	3546-27	Diazinon: 0.500 Pyrethrins: 0.025 Piperonyl butoxide: 0.262
	6218-69	Diazinon: 0.50 Pyrethrins: 0.05 Piperonyl butoxide: 0.26
	10088-71	Diazinon: 0.50 Pyrethrins: 0.05 Piperonyl butoxide: 0.26
	19713-317	Diazinon: 0.50 Pyrethrins: 0.05 Piperonyl butoxide: 0.125

Batch 15	EPA Reg. No.	% Active Ingredient
	239-2630	0.075
	67572-1	0.058

No Batch	EPA Reg. No.	% Active Ingredient
	239-2619	Diazinon: 0.50 Pyrethrins: 0.05
	270-260	Diazinon: 18.00 Piperonyl butoxide: 2.00
	829-249	25.00
	769-687	47.50

No Batch	EPA Reg. No.	% Active Ingredient
	1381-165	Diazinon: 15.52 Captan: 14.67 Lindane: 25.00 Metalaxyl: 1.00
	4691-142	20.00
	4691-148	40.00
	5481-241	Diazinon: 31.60 DDVP: 6.70
	5905-474	77.80
	6409-14	Diazinon: 0.500 Piperonyl butoxide: 0.128 Pyrethrins: 0.050 N-octyl bicycloheptene bicarboximide: 0.166
	7501-112	Diazinon: 15.00 Lindane: 25.00 Carboxin: 14.00
	8780-56	Diazinon: 2.10 Balan: 0.80
	13926-6	6.25
	34704-41	48.00
	39039-3	21.40
	39039-6	Diazinon: 30.00 Chlorpyrifos: 10.00
	42056-11	Diazinon: 15.00 Lindane: 25.00 Captan: 15.00
	42057-90	25.00
	45443-1	39.00
	53883-45	25.00